Patent

This listing of claims will replace all prior versions, and listings, of claims in the application:

Please cancel claims 1-26 and

Please add new claims 27-44.

Listing of Claims:

Claims 1-26 (CANCELED)

27. (NEW) A system for detecting glycated albumin in a sample and determining the percent glycated albumin comprising:

a first assay measuring glycated albumin in said sample;

a second assay measuring total albumin in the same sample as said first assay;

means for calculating percent glycated albumin.

28. (NEW) The system of claim 27 wherein said first assay comprises:
contacting a drop of blood with an anti-glycated albumin antibody such
that glycated albumin present in said blood binds to said anti-glycated albumin antibody;
and

detecting said bound glycated albumin.

- 29. (NEW) The system of claim 27 wherein said second assay comprises: contacting a drop of blood with an anti-albumin antibody such that albumin present in said blood binds to said anti-albumin antibody; and detecting said bound albumin.
- 30. (NEW) The system of claim 27 wherein said system is an immunochromatographic system.
- 31. (NEW) The system of claim 30 wherein said immunochromatographic system for determining the percent glycated albumin in a blood sample comprises:

a first test strip that measures glycated albumin and a second test strip that measures total albumin; and

a measurement device that reads, calculates and displays the result as the percentage of glycated albumin compared to total albumin in the sample.

- 32. (NEW) The system of claim 31, wherein said first test strip is comprised of microparticles coated with a first antibody to glycated albumin and an immobilization agent covalently bound to said test strip.
- 33. (NEW) The system of claim 32 wherein said immobilization agent is an antibody to glycated albumin.
- 34. (NEW) The system of claim 32 wherein said microparticles are selected from the group consisting of colloidal gold particles, latex particles, polystyrene particles, acrylic particles or other solid phase microparticles.
- 35. (NEw) The system of claim 31 wherein said second test strip is comprised of microparticles coated with a first antibody to albumin and a second antibody to albumin covalently bound to said test strip.
- 36. (NEW) The system of claim 35 wherein said microparticles are selected from the group consisting of colloidal gold particles, latex particles, polystyrene particles, acrylic particles or other solid phase microparticles.
- 37. (NEW) The system of either of claims 34 or 36, wherein said microparticles may be colored or tagged with a fluorescent compound.
- 38. (NEW) The system of claim 31 wherein the first test strip and the second test strip may be arranged in parallel; or opposite to each other; or at an angle to each other.
- 39. (NEW) The system of claim 31 wherein the first test strip and the second test strip are enclosed in a rigid cassette.
- 40. (NEW) The system of claim 31 wherein said measurement device is a reflectance spectrometer or a fluorometer comprising:
 - a detector for measuring the glycated albumin test result;
 - a detector for measuring the glycated albumin control band;
 - a detector for measuring the total albumin test result;
 - a detector for measuring the total albumin control band;

an internal computer chip for measurement and calculation;

- a liquid crystal display;
- an external port to transfer data to an external computer and/or printer;
- a battery and/or an external power source; and
- a rigid external case with an aperture for inserting the test cassette.
- 41. (NEW) The system of claim 40 whereby the one or more than one test result can by displayed on said measurement device's liquid crystal display in numerical format or in graphical format.
- 42. (NEW) The system of claim 40 further comprising an internal memory chip capable of storing one or more than one test result.
- 43. (NEW) The system of claim 42 whereby the one or more than one test result can be transferred to an external computer or printer.
- 44. (NEW) A method of monitoring glycated albumin using a point-of-care assay and determining a percent glycated albumin level comprising:

depositing a drop of blood into a sample well of an immunochromatography system test cassette;

transferring said blood into the sample application pad thereby allowing blood plasma to pass into a first conjugate pad of a first test strip and into a second conjugate pad of a second test strip;

binding said blood plasma to anti-glycated albumin antibody-coated microparticles in said first conjugate pad;

binding said blood plasma to anti-total albumin antibody-coated microparticles in said second first conjugate pad;

allowing blood plasma-bound antibody-coated microparticles to migrate across said conjugate pad to a fixed band of membrane-bound antibody;

binding said blood plasma-bound antibody-coated microparticles to said membrane bound antibody to form a visible band;

inserting said immunochromatography system test cassette into a measurement device;

providing numerical results of glycated albumin levels from said first test

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Patent 51328-00001

strip and total albumin levels from said second test strip; and calculating said percent glycated albumin.